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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,169	04/19/2001	Theresa Ann Jeary	P24,622 USA	3922

7590

09/11/2003

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/11/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,169	JEARY ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 20-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 20-23 and 25-40 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt is acknowledged of applicant's Request for Extension of Time, Request for Continued Examination, and Information Disclosure Statement filed 05/15/03.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/15/03 has been entered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 21, 23, 25, and 28-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman EP 0 797 991 A1.

Sherman teaches an extended release composition comprising an antidepressant in a form of coated beads or spheroids (page 3, lines 13-30). The coated beads filled into hard gelatin capsules having a release profile as showed in

table 1 (pages 3-4). Sherman also teaches that the dosage form is a 24 hours extended release formulation (abstract).

Claims 1-5, 21, 23, 25, and 28-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Norling et al. US 5,958,458.

Norling teaches a pharmaceutical multiparticulate formulation in the form of coated cores (abstract). The core is in the form of pellets, comprising active agent and excipient (columns 2, lines 33-42; and column 13, lines 29-67). The active agent including antidepressants (column 6, lines 35-40). The coated multiparticulate is formulated to release active agent during a 24 hours period (column 13, lines 20-36). Suitable coating polymers including ethyl cellulose, Eudragit®, polyvinyl acetate phthalate (columns 9-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 20-23, 25, and 30-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman EP 0 797 991 A1, in view of Zentner et al. US 4,851,228.

Sherman is relied upon for the reason stated above. Sherman does not teach the specific antidepressant drug, such as fluvoxamine as claimed in claim 22.

Zentner teaches multiparticulate controlled delivery system comprising active core coated with rate controlling water insoluble wall (column 2, lines 57 through column 3, lines 1-10; column 10, lines 59 through column 11, lines 1-51). The active agent in the core including antidepressant, *e.g.*, fluvoxamine (column 14, lines 4-13). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify the extended release formulation of Sherman using fluvoxamine as an antidepressant in view of the teaching of Zentner, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

Claims 1-5, 20-23, and 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman EP 0 797 991 A1, in view of Van Balken et al. US 6,183,780.

Sherman is relied upon for the reasons stated above. Sherman does not teach the specific antidepressant drug, such as fluvoxamine as claimed in claim 22.

Van Balken teaches an oral delayed immediate release formulation comprising active core coated with rate control release polymer (columns 5-6). The active agent in the core is an antidepressant, *e.g.*, fluvoxamine (column 5, lines 24-25). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to modify the extended release formulation of Sherman using fluvoxamine as an antidepressant in view of the teaching of Van Balken, because the references teach that antidepressant can be

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incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

Claims 1-5, 20-23, and 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norling et al. US 5,958,458, in view of Van Balken et al. US 6,183,780.

Norling is relied upon for the reason stated above. Norling is silent as to the specific teaching of antidepressant drug, such as fluvoxamine as claimed in claim 22.

Van Balken teaches an oral delayed immediate release formulation comprising active core coated with rate control release polymer (columns 5-6). The active agent in the core is an antidepressant, e.g., fluvoxamine (column 5, lines 24-25). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify pharmaceutical multiparticulate formulation of Norling using fluvoxamine as an antidepressant in view of the teaching of Van Balken, because the references teach that antidepressant can be incorporated in an extended release formulation, such as coated beads/pellets. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

Response to Arguments

Applicant's arguments filed 01/23/03 have been fully considered but they are not persuasive.

Applicant argues that Zentner teaches fluvoxamine in a lengthy list of drugs. None of the examples discloses the use of fluvoxamine or any other SSRI. However, if the reference's disclosed range is so broad as to encompass a very large number of possible distinct compositions, this might present a situation analogous to the obviousness of a species when the prior art broadly discloses a genus. *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994). Zentner is relied upon solely for the teaching of fluvoxamine is a well-known antidepressant.

Claims Allowable

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson et al. and Zemlan et al. are cited as being of interest for the teaching of an enteric pellet comprising a core containing fluoxetine.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-

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5816. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

THURMAN K. PAGE, J.D.
SUPERVISORY PATENT EXAMINER